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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/791,173	03/02/2004	Frank A. Chan	7404-613	3173
<p>7590 01/05/2007 Woodard, Emhardt, Moriarty, McNett & Henry LLP Bank One Center/Tower Suite 3700 111 Monument Circle Indianapolis, IN 46204-5137</p>			EXAMINER LANG, AMY T	
			ART UNIT 3731	PAPER NUMBER
SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE		
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Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)
	10/791,173	CHAN, FRANK A.
	Examiner	Art Unit
	Amy T. Lang	3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on ____.
 2a) This action is FINAL. 2b) This action is non-final.
 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 1-23 is/are pending in the application.
 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
 5) Claim(s) ____ is/are allowed.
 6) Claim(s) 1-23 is/are rejected.
 7) Claim(s) 6 is/are objected to.
 8) Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
 10) The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. ____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>9/15/05, 3/2/04</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Specification

1. **Claim 6** is objected to because of the following informalities: An apparatus and a method are claimed together and should be separated. The apparatus, as disclosed in claim 1 is defined by "obtaining a sample of bodily fluid through the skin." The method is defined by the step wherein the electrical energy "is applied." Appropriate correction is required.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. **Claim 9** recites the limitation "said units" in line 1 of the claim. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

4. Claims 1-5, 7, 9, 10, 12, and 15-18 are rejected under 35 U.S.C. 102(e) as being anticipated by Lipoma (US 2004/0254599 A1).

With regard to **claims 1 and 10**, Lipoma discloses a lancing device for drawing a body fluid while reducing associated pain ([0002]). The device, as shown in Figure 67, comprises a housing, a lancet (844) and transducers (811) ([0156]). Although Lipoma refers to Figure 66 when disclosing the lancet device comprised of transducers, it is the examiner's position that Lipoma intended to refer to Figure 67 since Figure 66 discloses a syringe. The transducers are further disclosed as electrodes connected to a battery, which overlaps the instantly claimed electrical signal generator ([0157]). The battery delivers sufficient energy to stimulate the skin and reduce pain ([0159]).

With regard to **claim 15**, Lipoma discloses that first the skin nerves are stimulated and then the lancing tip is inserted ([0110]).

With regard to **claims 2, 3, and 16**, as shown in Figure 67, the electrodes (811) are positioned in an array surrounding the lancing site.

With regard to **claims 4 and 17**, Lipoma further discloses the battery as supplying an AC signal ([0158]).

With regard to **claims 5 and 18**, since the quantity of electrical energy supplied is sufficient to stimulate the skin, it is inherently less for engorgement than pain masking.

With regard to **claim 9**, as shown in Figure 67, Lipoma discloses four electrodes surrounding the lancing tip. Therefore, two pairs of electrodes are disclosed in an array surrounding the lancing site.

With regard to **claims 7 and 12**, Lipoma discloses that the type, spacing, and position of the electrode may be varied ([0158]). Therefore, the device is inherently adapted to adjust the level of electrical energy and provide electrical energy for at least one minute.

Claim Rejections - 35 USC § 103

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

6. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

7. **Claims 6, 8, 9, and 19- 21** are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipoma (US 2004/0254599 A1).

With regard to **claims 6, 8, and 19-21**, Lipoma discloses a device that applies electrodes to a lancing site to reduce pain. However, Lipoma fails to disclose the instantly claimed voltage, current, and duration. The instant disclosure describes this parameter as merely preferable and does not describe it as contributing any unexpected

result to the lancing device. As such this parameter is deemed a matter of design choice (lacking in any criticality) and well within the skill of the ordinary artisan, obtained through routine experimentation in determining optimum results.

With regard to **claim 9**, Lipoma discloses that the number and spacing of electrodes on the device may be varied ([0158]). Therefore, it would have been to one of ordinary skill at the time of the invention for the transducers to be arranged in a plurality of electrode pairs

8. **Claims 1-22** are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuriger (US 2004/0267299 A1) in view of Lipoma (US 2004/0254599 A1).

With regard to **claims 1-3, 10, and 16**, Kuriger discloses a lancing device that reduces pain when utilizing the device ([0001]). The device comprises a lancing device (16), a body (12), which overlaps the instantly claimed housing, and a vibration member (18) powered by a battery ([0017], [0018], [0025]). As shown in Figure 5, the vibration member is arranged in an array to surround the lancing tip. This component contacts the skin and stimulates nerves to reduce pain sensation associated with the lancing tip ([0023]).

Kuriger does not specifically disclose the vibration member as comprised of electrodes. Lipoma also discloses a lancing device with transducers for stimulating the skin at the lancing site ([0156], [0157]). The transducers are further disclosed as electrodes, which, as shown in Figure 67, also surround the lancing tip in an array ([0157]). Therefore, since both Kuriger and Lipoma disclose a component to stimulate

skin at a lancing site for pain reduction, it would have been obvious to one of ordinary skill at the time of the invention for Kuriger to also utilize electrodes as disclosed by Lipoma since they effectively reduce perceived skin pain.

With regard to **claim 15**, Kuriger discloses that the vibration member is applied during the lancing process ([0022]). However, Kuriger is silent regarding the order of the method steps. Lipoma discloses that first the skin nerves are stimulated and then the lancing tip is inserted ([0110]). Since both Kuriger and Lipoma disclose the same method and Kuriger does not disclose the order of method steps, it would have been obvious to one of ordinary skill at the time of the invention for Kuriger to also utilize the method order of Lipoma.

With regard to **claim 7**, since the electrical signal generator comprises a battery, the device is intrinsically adapted to apply electrical energy for at least one minute.

With regard to **claims 4 and 17**, the electrical signal generator powering the vibration member is disclosed as supplying an AC signal ([0029]).

With regard to **claims 5 and 18**, since the quantity of electrical energy supplied is sufficient to stimulate the skin, it is inherently less for engorgement than pain masking.

With regard to **claims 6, 8, 11, 12, and 19-22**, Kuriger discloses that the amount of power applied to the vibration member may vary and that the patient may adjust the amount of power delivered ([0025]). Therefore, the level of electrical energy of the signal generator is adjustable. Furthermore, it would have been obvious to one of ordinary skill at the time of the invention for the patient to adjust the voltage, current, and time to overlap the instant claims absent evidence to the contrary.

With regard to **claim 9**, as shown in Figure 5, Kuriger discloses six electrodes surrounding the lancing tip. Therefore, three pairs of electrodes are disclosed in an array surrounding the lancing site.

With regard to **claims 13 and 14**, Kuriger further discloses an electrochemical biosensor that monitors the blood ([0033] – [0036]). The biosensor is either integrated into the lancet device or as a separate device ([0034]). Therefore, it would have been obvious for the biosensor to be adjacent to the lancing device and in communication via a capillary passage.

9. **Claim 23** is rejected under 35 U.S.C. 103(a) as being unpatentable over Lipoma (US 2004/0254599 A1) in view of Erickson (US 2004/0087873 A1) or Kuriger (US 2004/0267299 A1) in view of Lipoma (US 2004/0254599 A1) and Erickson (US 2004/0087873 A1).

Both Lipoma and Kuriger disclose a lancing device for drawing a body fluid. However, neither Lipoma nor Kuriger disclose compressing the lancing site after drawing the fluid. Erickson teaches that once a device is inserted into the skin for drawing a fluid, compressing the skin around the device aids in drawing the fluid into the device ([0064]). Therefore, since compressing the skin is taught as advantageously aiding to draw a fluid into a device, it would have been obvious to one of ordinary skill of the art at the time of the invention for either Lipoma or Kuriger to also compress the skin after inserting the lancing device into the skin.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Amy T. Lang whose telephone number is 571-272-9057. The examiner can normally be reached on M-F 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on 571-272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

12/22/06

ATL


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12/22/06